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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,546	06/04/2001	Gcoff J. Clark	NIH-05080	7592
23535	7590	04/08/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			SCHNIZER, RICHARD A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/873,546

Applicant(s)

CLARK ET AL.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: Claims 1, 2, and 4 as amended introduce new matter into the disclosure. These claims are drawn to recombinant expression vectors consisting of an open reading frame encoding SEQ ID NO:5 operably linked to one or more regulatory elements. The specification as filed does not provide written support for any vector consisting only of regulatory sequences operably linked to a nucleic acid encoding SEQ ID NO:5. It is conventional within the art to use viral vectors (e.g. gutted viral vectors) that comprise only regulatory sequences that affect the expression or replication of heterologous genes of interest. For example, the specification discloses the use of adeno-associated virus vectors which typically are used without any viral genes and which would meet the limitations of the claims. However, claims 1, 2, and 4 are not limited to viral vectors, and the specification contemplates plasmid vectors and other non-viral vectors broadly such that these claims could fairly be interpreted as being drawn to plasmid or cosmid vectors consisting only of regulatory sequences in operably linkage with a nucleic acid encoding SEQ ID NO:5. But, the specification fails to teach any such non-viral vector, e.g. the specification fails to teach a plasmid expression vector lacking a selectable marker, although it is conventional in the art for such elements to be included in plasmid expression vectors. For these reasons, claims 1, 2, and 4 are considered to comprise new matter. These amendments were also not entered because they would have necessitated new search and consideration, i.e. because the claims would overcome the standing 102 rejection, it would be necessary to determine whether or not it would be obvious to subclone the open reading frame of Lamerdin into e.g. an adeno-associated viral vector.

Continuation of 5. does NOT place the application in condition for allowance because: The amendments were not entered. Even if the amendments to claims 6-16 and 29 had been entered, the 103 rejections of these claims based on Lamerdin would be maintained. Applicant's argument at page 10 of the response that Lamerdin fails to teach a recombinant expression vector consisting of an open reading frame encoding SEQ ID NO:5 operably linked to one or more regulatory elements is unpersuasive because the rejected claims do not recite this limitation. Applicant's arguments regarding the motivation to combine the cited references are unpersuasive because Applicant has not addressed the reasons for motivation set forth in the rejections. Applicant's arguments stating that the cited references fail to teach every element of the claims are unpersuasive because Applicant has not identified any element that the combined references fail to teach.

DAVE T. NGUYEN
PRIMARY EXAMINER

